

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 10 and 12-17 are pending in the application, with claim 10 being the independent claim. Claims 1-9 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 14-17 are sought to be added. Support for the amendment to claim 10 and new claim 14 can be found on page 17, line 5, and page 17, line 6, respectively, of the specification as filed. Support for new claim 15 can be found in Table A on page 37 of the specification as filed. Support for new claim 16 can be found at page 17, line 6, of the specification as filed. Support for new claim 17 can be found in Table A on page 37 of the specification as filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Applicants thank the Examiner for indicating that the invention comprising controlling *Plutella* with a composition comprising 0.8 ppm of the compound of formula (I-4) and 0.0064 ppm of the compound of formula (II-1) would be allowable.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Description of the Invention

The present invention relates to novel active compound combinations comprising a compound of formula (I-4) and a compound of formula (II-1), suitable for controlling animal pests such as insects and acarids.

Rejection under 35 U.S.C. § 112

Claims 1-10, 12 and 13 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection. Cancellation of claims 1-9 renders their rejection moot.

Specifically, the Examiner states that

the specification while providing enablement for 1) the combination of 0.8 ppm compound I-4 and 0.0064 ppm compound II-4 and 2) the control of *Plutella* using 0.8 ppm of compound I-4 plus 0.0064 ppm of compound II-1, does not reasonably provide enablement for the control of *Plutella*[sic] using other amounts of compound I-4 and II-1. In addition, the specification does not provide enablement for any other claim combination of compound I and compound II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

Office Action at page 2.

Applicants respectfully disagree. The enablement of claims 10, 12, and 13, and the newly added claims 14-17, is supported by the specification as filed at the time the above-captioned application was filed for at least the following reasons.

The enablement requirement of § 112, first paragraph, ensures that one skilled in the art will be able to make and use the invention. Further, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *See* M.P.E.P. § 2164.01. "[A] considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

As supported by case law, Applicants need not supply information that is well known in the art. *See In re Horwath*, 654 F.2d 103, 105-6, 210 U.S.P.Q. 689, 692 (C.C.P.A. 1981); *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d at 1366, 42 U.S.P.Q.2d at 1005 (Fed. Cir. 1997); and *In re Brebner*, 455 F.2d 1402, 173 U.S.P.Q. 169 (C.C.P.A. 1972).

Further, it is well established that satisfaction of the enablement requirement pursuant to 35 U.S.C. § 112, first paragraph, does not require that an Applicant make and test all species encompassed by a generic claim. *See In re Angstadt*, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976); *see also*, M.P.E.P. § 2164.06.

It is respectfully submitted that given the knowledge possessed by one of ordinary skill in the art and the teachings of the present specification, only routine experimentation would have been required for making and using the compounds as claimed at the time the application was filed.

The Examiner considered the *In re Wands* factors as follows:

1) Scope or breadth of the claims

Regarding the breadth of the claims, the Examiner states that the "claims are broader in scope than the enabling disclosure. Applicant is purporting: enablement for all combinations of compound I and II." (Office Action at page 3). Applicants respectfully disagree with the Examiner's assertion as it applies to the claims as amended. Claim 10 has been amended to require a composition comprising a compound of formula (I-4) and a compound of formula (II-1) at a ratio of 250:1 to 1:50. Applicants submit that the breadth of the claims as amended does not render the claims non-enabled.

While the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'," not everything necessary to practice the invention need be disclosed. *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated that a "demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." Accordingly, an inventor need not be limited to claiming only those materials and processes which will work and need not disclose what is well-known and is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further, the scope of

enablement must only bear a "reasonable correlation" to the scope of the claims. *See, e.g., In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The specification provides description of compositions for controlling animal pests comprising a compound of formula (I-4) and (II-1). Example A of the specification is illustrative of the insecticidal activity of the claimed composition. As such, Applicants believe that they have demonstrated a reasonable correlation between the scope of enablement and the scope of the claims.

2) *Nature of the invention*

Regarding the nature of the invention, the Examiner characterizes the invention to be of "an invention comprising known compound I and known compound II." (Office Action at page 3). Applicants respectfully submit that, in light of the amended claims, the invention is a composition comprising a compound of formula (I-4) and a compound of formula (II-1) at a ratio of 250:1 to 1:50. In addition to the above, the invention is directed to a method of controlling animal pests and a process for preparing an insecticidal and acaricidal composition.

4) *State of, or the amount of knowledge in, the prior art*

The Examiner cites Fischer *et al.* (WO 02/30199, English equivalent: US 2004/0102326) ("Fischer") and Sakata *et al.* (WO 02/87334, English equivalent: US 2004/0077500) ("Sakata") for the proposition that compounds I-4 and II-1 are disclosed in the prior art. The Examiner further states that "[i]t would have been obvious to modify the invention taught by Fischer et al. [sic] to include the compound 133 taught by Sakata et al. One would have been motivated to do this since both active compounds individually have insecticidal and acaricidal activity." (Office Action, page 4).

Applicants respectfully disagree and submit that the Examiner is incorrectly applying the standards for determining obviousness to the enablement rejection.

6) *Amount of guidance or direction provided by the inventor*

The Examiner asserts that "[a]pplicant was required to provide in the specification additional guidance and direction with respect to how [to] use the claimed subject matter in order for the application to be fully enabled. Applicants respectfully disagree with the Examiner's assessment.

The specification describes that the compositions of the present invention exhibit favorable pesticidal activity. See page 17, line 9 through page 20, line 29, of the specification. The specification also discloses several methods for controlling animal pests on page 32, line 34 through page 33, line 2, including methods of administration and dosages. Further, Example A demonstrates methods for controlling insects by using a composition of the invention. Thus, the specification teaches methods for controlling animal pests using compositions of the present invention.

Further, the Examiner has provided no reason why a person skilled in the art would question the activity of compositions of the present invention, wherein the ratio of the compound of formula (I-4) and the compound of formula (II-1) is other than that described in Example A, i.e., other than 0.8 ppm of compound (I-4) and 0.0064 ppm of compound (II-1). Additionally, assuming that there were inoperative embodiments, it is not the function of generic claims to exclude any potential inoperative embodiments. So long as there is sufficient guidance in the specification, and the amount of

experimentation to test a particular compound on a particular pest is not undue, then enablement is satisfied.

7) *Presence or absence of working examples*

The Examiner states that the "specification fails to provide scientific data and working embodiments with respect to an invention control of Pluetall [sic] using amounts of compound I-4 other than 0.8 ppm and compound II-1 other than 0.0064 ppm." (Office Action, page 4). It is respectfully submitted that the guidance provided in the specification is sufficient to enable one of ordinary skill to practice the invention of the present claims without undue experimentation. Applicants respectfully submit that there is no issue of undue experimentation as it relates to the working example and using compositions of the present invention for controlling animal pests. Applicants also submit herewith a Declaration under 37 C.F.R. § 1.132 (described in detail below), which sets forth additional examples of compositions of the present invention.

8) *Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure*

The Examiner states that "[o]ne of ordinary skill would have to conduct time-consuming and costly experimental methods to determine which combinations (including amounts) of compound I and compound II show unexpected activity (including which pests)." (Office Action, page 5) Applicants respectfully disagree. The present claims as amended are directed to a composition comprising a compound of formula (I-4) and (II-1) at a ratio of 250:1 to 1:50, and use thereof as a pesticide or an acaricide. Applicants submit that the guidance provided in the specification, along with the working example is sufficient to make and use the claimed invention.

Applicants respectfully request that this rejection of claims 1-10, 12 and 13 under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn. Claims 1-9 have been canceled.

Rejection under 35 U.S.C. § 103

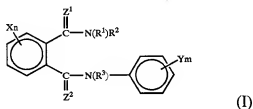
Claims 1-10, 12 and 13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fischer and Sakata. Applicants respectfully traverse this rejection. Cancellation of claims 1-9 renders their rejection moot.

In rendering the rejection, the Examiner states that Fischer *et al.* teach compound I-4 and Sakata *et al.* teach compound II-1. Examiner alleges that "it would have been obvious to modify the invention taught by Fischer *et al.* [sic] to include the compound 133 taught by Sakata *et al.* One would have been motivated to do this since both active compounds individually have insecticidal and acaricidal activity." Office Action, p. 6. Applicants respectfully disagree.

Applicants submit that none of claims 10, 12 and 13 is *prima facie* obvious in view of the cited references. Fischer purportedly describes active compound combinations of cyclic ketonols with a variety of fungicides, *i.e.*, azoles, strobins, dithiocarbamates, halogenoalkylsulphenamides and -imides, N-phenylamino-heterocycles, phenethylamides, N-3,5-dichlorophenylheterocycles, sulphonames, *etc.* to obtain combinations having fungicidal, insecticidal and acaricidal activities. Thus, Fischer discloses a large number of combinations comprising cyclic ketonols. The Examiner has not articulated a reason why a person of ordinary skill in the art would select the compound I-4 from Fischer. Further, even though Fischer specifically

discloses compound I-4, it does not teach combining compound I-4 with compound II-1 at the ratio recited in the pending claims.

Sakata does not cure the deficiencies of Fischer. Sakata purportedly describes a pest control agent composition having a compound of general formula (I)



wherein the substituents X_n , Z^1 , Z^2 , R^1 , R^2 , R^3 and Y_m are selected from a large number of substituents. (Sakata, ¶¶ [0006]-[0024].) Thus, Sakata generally describes hundreds of thousands of compounds. Furthermore, compound II-1 is one among a list of 142 specifically disclosed compounds in Table 1 of Sakata. (Sakata, pages 5-7.) The Examiner has not articulated a reason why a person of ordinary skill in the art would pick compound II-1 from among the 142 specifically disclosed compounds of Sakata. Further, even though Sakata specifically discloses compound II-1, it does not teach compound II-1 in combination with compound I-4 from Fischer at the ratio recited in the pending claims.

Under *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q. 2d 1385, 1741 (USSC) (2007), "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art." Rather, there must be a reason or rationale behind an obviousness determination and "this analysis should be made explicit." *Id.* Hence, under KSR, the

mere fact that the individual elements, i.e., compound I-4 and compound II-1 were independently known in the art does not render present claims 10, 12 and 13 obvious. The Office is using impermissible hindsight analysis to piece together isolated elements taken from Fischer and Sakata, using Applicants' disclosure as a blueprint to arrive at the presently claimed composition. Neither Fischer nor Sakata provide any reason for a person of ordinary skill in the art to combine the two compounds as recited in instant claim 10.

Applicants are aware of the flexible approach for establishing obviousness set out in *KSR*. However, as cautioned by Judge Rader in a post-*KSR* decision in *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009), "where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness." (561 F.3d at 1359.) The Examiner has not provided any reason for a person of ordinary skill in the art to specifically select compound I-4 from Fischer and compound II-1 from Sakata from among all the available compounds in order to arrive at the composition of the instant claims.

In addition, the pending claim 10 requires a range of certain weight ratio of compound (I-4) to compound (II-1). Fischer and Sakata are completely silent with respect to the recited weight ratio. Applicants respectfully submit that to establish *prima facie* obviousness of a claimed invention, all claim limitations must be considered (*See* M.P.E.P. 2143.03).

The Examiner appeared to take the position that the claimed combinations are obvious because Fischer and Sakata disclose the individual members of the composition. Applicants respectfully disagree.

Fischer and Sakata's disclosure of the two compounds does not in and of itself compel a finding the obviousness of the present invention. As explained in detail below, Applicants have demonstrated a synergistic effect obtained from the claimed combinations in controlling different pests, employing various ratios of the active agents.

In sum, there is nothing in any of the cited references that would have provided a reason for making the composition as recited in the present claim 10. Accordingly, the Examiner has not established a *prima facie* case of obviousness of claim 10. Further, the Examiner has not established a *prima facie* case of obviousness of claim 12 or claim 13.

Even assuming, *arguendo*, that a *prima facie* case of obviousness has been established, which it has not, the synergistic effect exhibited by the claimed invention is sufficient to rebut a *prima facie* case of obviousness.

Applicants submit that the present invention possesses a synergistic effect as shown in the specification at Table A. The specification demonstrates that compound I-4 and compound II-1, when applied in combination in amounts of 0.8 ppm and 0.0064 ppm, respectively, (i.e., at a ratio of 125:1), exhibit a higher insecticidal activity than predicted by the Colby formula. In Example A, cabbage leaves (*Brassica oleracea*) are treated by being dipped into the preparation of active compound of the desired concentration and are populated with caterpillars of the diamondback moth

(*Plutellaxylostella*) while the leaves are still moist. The kill rate in % is determined after 6 days.

As shown in Table A, when compound I-4 and compound II-1 are applied individually at concentrations of 0.8 ppm and 0.0064 ppm, respectively, each exhibits an efficacy of 0% and 30%. However, an efficacy of 60% was observed when the combination was tested. Thus, the efficacy of the tested composition was synergistic according to the Colby formula.

Applicants also submit herewith a Declaration under 37 C.F.R. § 1.132 ("Declaration") which demonstrates the higher than expected activity of the claimed mixtures. In the Declaration, Ms. Hungenberg recites results obtained from comparing the application of single compounds to the application of mixtures of compounds according to the present claims. The results therein illustrate that a combination according to the present invention is superior to the individual compounds applied alone.

In Example A of the Declaration, cabbage leaves were treated by spraying with a 100 ppm spirotetramat (i.e., compound (I-4)) preparation, or a 4 ppm flubendiamid (i.e., compound (II-1)) preparation, or a preparation having a combination of the two compounds at a ratio of 25:1 (100 ppm:4 ppm, respectively). The leaves were then infested with larvae of the mustard beetle (*Phaedon cochleariae*). After 3 days, the per cent mortality was measured for each test. According to the Colby formula, the 25:1 mixture of spirotetramat and flubendiamid provided a synergistic effect compared to the single compounds. The combination exhibited a 65% mortality rate after 3 days

compared to a 0% mortality for each of the compounds alone or a predicted 0% mortality for the mixture.

In Example B of the Declaration, cabbage leaves were treated by spraying with a 0.8 g/ha spirotetramat preparation, or a 0.8 g/ha flubendiamid preparation, or a preparation having a combination of the two compounds at a ratio of 1:1 (0.8 g/ha:0.8 g/ha, respectively). The leaves were then infested with larvae of the fall army worm (*Spodoptera frugiperda*). After 6 days, the per cent mortality was measured for each test. According to the Colby formula, the 1:1 mixture of spirotetramat and flubendiamid provided a synergistic effect compared to the single compounds. The combination exhibited a 83% mortality rate after 6 days compared to a 50% predicted mortality for the mixture.

In Example C of the Declaration, bean plants which were heavily infested by the two-spotted spider mite (*Tetranychus urticae*) were treated by spraying with a 100 ppm or 20 ppm spirotetramat preparation, or a 100 ppm flubendiamid preparation, or a preparation having a combination of the two compounds at a ratio of 1:1 (100 ppm:100 ppm, respectively) or 1:5 (20 ppm:100 ppm, respectively). After 1 day, the per cent mortality was measured for each test. According to the Colby formula, both the 1:1 and 1:5 mixtures of spirotetramat and flubendiamid provided a synergistic effect compared to the single compounds. The 1:1 combination exhibited a 40% mortality rate after 1 day compared to a 20% predicted mortality for the mixture, while the 1:5 combination exhibited a 25% mortality rate after 1 day compared to a 10% predicted mortality for the mixture.

Reply to Office Action of February 28, 2011

FISCHER *et al.*
Appl. No. 10/563,794

For the reasons set forth above, Applicants respectfully request that the Examiner reconsider the evidence of unexpected synergistic effect presented in the specification and in the Declaration, and that this rejection of claims 1-10, 12, and 13 under 35 U.S.C. § 103(a) be withdrawn. Claims 1-9 have been cancelled.

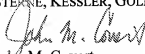
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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